REMARKS

1. Applicant thanks the Examiner for his detailed findings and conclusions.

2. It should be appreciated that the Applicant has elected to amend Claims 1, 15, 17, 28, 32, and 33 solely for the purpose of expediting the patent process in a manner consistent with the PTO's Patent Business Goals, 65 Fed. Reg. 54603 (9/8/00). In making such amendments, Applicant has not and does not in any way narrow the scope of protection to which the Applicant considers the invention herein entitled. Rather, Applicant reserves Applicant's right to pursue such protection at a later point in time and merely seeks to pursue protection for the subject matter presented in this submission.

Hilton Davis / Festo Statement

The amendments herein to Claims 1, 15, 17, 32, and 33 were not made for any reason related to patentability. Claims 1, 15, 17, 32, and 33 were amended to clarify the invention. Claim 28 was amended to conform with standard claim drafting practices. All of the above listed amendments were made for reasons other than patentability.

3. Claims 1-6, 8-17, 21-26, 28-30, 32, and 33 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that the Applicant regards as the invention.

Claim 1

The Examiner states that the clause "abstract representation" is vague and indefinite. Respectfully, the Applicant disagrees. However, in order to expedite the patent prosecution process in a manner consistent with the PTO's Patent Business Goals, 65 Fed. Reg. 54603 (9/8/00), the Applicant amends Claim 1 to remove the "abstract" term. Accordingly, the current rejection of Claim 1 as being vague and indefinite due to use of the term "abstract" is deemed to be overcome.

Claim 32

The Examiner states that the clause "unsupervised classification" is vague and indefinite. Respectfully, the Applicant disagrees. However, the Applicant amends Claim 32 to further require that an unsupervised classification uses an exemplary set of features to explore and develop clusters of data in feature space, where the data is the glucose concentration profile. Support for the amendment is found in the application as filed at least at page 26, lines 10-11 reading: "Unsupervised methods rely solely on the exemplary set of features to explore and develop clusters or natural groupings of the data in feature space". Accordingly, the current rejection of Claim 32 as being vague and indefinite due to use of the clause "unsupervised classification" is deemed to be overcome.

Claim 33

The Examiner states that the clause "supervised classification" is vague and indefinite. Respectfully, the Applicant disagrees. However, the Applicant amends Claim 33 to further require that a supervised classification defines a class of the screening factor through known differences in data, where the data is the glucose concentration profile. Support for the amendment is found in the application as filed at least at page 26, lines 5-6 reading: "In the supervised case, classes are defined through known differences in the data". Accordingly, the current rejection of Claim 33 as being vague and indefinite due to use of the clause "supervised classification" is deemed to be overcome.

3. Claims 1-6, 8-17, 21-26, 28-30, 32, and 33 stand rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter.

Claims 1-6, 8-17, 21-26, 28-30, 32, and 33

As to Claims 1-6, 8-17, 21-26, 29-30, 32, and 33 the Applicant respectfully disagrees. However, in order to expedite the patent prosecution process, the Applicant amends Claims 1, 15, 17, and 33 to provide clear U.S.C. § 101 support. Following the Examiner's helpful suggest, the Applicant amends Claims 1, 15, 17, and 33 to require a step of outputting the determined state of glucose metabolism disorder to a display,

thereby providing a tangible result. Accordingly, the current rejection of Claims 1, 15, 17, and 33 and all claims dependent therefrom under 35 U.S.C. § 101 as being directed to non-statutory subject matter is deemed to be overcome.

4. The Applicant further amends Claim 15 to correct a grammatical punctuation error according to standard claim drafting practices.

5. Claims 1-6, 8-16, 21-27, 29, 30, 32, and 33 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. patent no. 6,925,393 (hereinafter "Kalatz").

Claims 1, 15, and 33

As to Claims 1, 15, and 33 the Applicant respectfully disagrees. Claims 1, 15, and 33 require that the subject is classified into a state of glucose metabolism disorder, where the disorder comprises any of (1) a diabetic or (2) pre-diabetic condition. These conditions describe the chronic state of the illness diabetes mellitus. In stark contrast, the Examiner cited section of Kalatz, at column 7, lines 65-67 and column 8, lines 1-8 teaches Kalatz as determining an acute glucose concentration. Respectfully, terminology describing a chronic state of the disease diabetes mellitus is distinctly different from determining an acute localized in time glucose concentration. Accordingly, the current rejection of Claims 1, 15, and 33 and all claims dependent therefrom under 35 U.S.C. § 102(e) as being anticipated by Kalatz is deemed to be improper.

However, in order to expedite the patent prosecution process, the Applicant further amends Claims 1, 15, and 33 to clarify the invention in several parts. First, the Applicant amends Claims 1, 15, and 33 to remove the hyperinsulinemic option as hyperinsulinemia refers to an acute condition classifying an individuals response to a meal and is not to a state of glucose metabolism disorder as used herein. Second, the Applicant amends Claims 1, 15, and 33 to clarify that the state of glucose metabolism is a chronic condition. Third, the Applicant amends Claims 1, 15, and 33 to clarify that the state of glucose metabolism disorder is classified as any of (1) a diabetic condition and

(2) a pre-diabetic condition of diabetes mellitus. Support for the amendment is found in the application as filed at least at page 1, line 24 reading "diabetes is a chronic ... disease" and at page 2, lines 13-20 reading in part with underlining emphasis added: "TYPE I – INSULIN DEPENDENT DIABETES MELLITUS ... Type I diabetes is an autoimmune disease .... [p]eople with this condition require daily doses of insulin to stay alive". As amended, Claim 1 clearly articulates that the method classifies the subject into a chronic condition, where the chronic condition is either (1) a diabetic condition or (2) a pre-diabetic condition of diabetes mellitus. A chronic classification of the disease diabetes mellitus is distinct from an acute measurement of a glucose concentration. In stark contrast to the Claim 1, 15, and 33 classification of type of diabetes mellitus, which is a disease classification characterizing a person for years, Kalatz merely determines a glucose concentration state, which is a reading for a given point in time. In short, a glucose concentration is distinct from a disease classification. Accordingly, the current rejection of Claims 1, 15, and 33 and all claims dependent therefrom under 35 U.S.C. § 102(e) as being anticipated by Kalatz is deemed to be overcome.

6. Claims 1-16, 21-26, 28-30, 32, and 33 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. patent no. 6,518,069 (hereinafter "Otvos").

Claims 1, 15, and 33

In view of the above described amendments to parent Claims 1, 15, 33, the current rejection of Claims 1, 15, and 33 and dependent Claims 2-14, 16, 21-26, 28-30, and 32 under 35 U.S.C. § 102(e) as being anticipated by Otvos is rendered moot.

Claims 1 and 15

Further, The Applicant amends Claims 1 and 15 to further require that the step of measuring is performed noninvasively. Support for the amendment is found in the application as filed at least at page 11, lines 20-21 reading "it is preferable that the glucose measurements be made with a non-invasive analyzer". Those skilled in the art

will immediately understand that a noninvasive blood glucose analyzer does not use a blood sample drawn from the body. Further, dictionary.com defines noninvasive as:

> **non·in·va·sive** Not penetrating the body, as by incision or injection: *noninvasive surgery; a noninvasive diagnostic method.*

Hence, by both definition and as known by those skilled a noninvasive analyzer does not use a blood sample drawn from the body. In stark contrast, Otvos teaches in the abstract that , emphasis added: "A patient blood sample is collected and NMR derived patient spectrums for the blood sample are obtained. [and] The glucose concentration can be evaluated with a blood sample". An invasive measurement as taught by Otvos starkly contrasts with the amended claim requirement of a noninvasively measuring a glucose concentration profile. Accordingly, the current rejection of Claims 1 and 15 and all claims dependent therefrom under 35 U.S.C. § 102(e) as being anticipated by Otvos is deemed to be overcome.

Claim 1

The Applicant still further amends Claim 1 to require the step of generating a screening factor to generate the screening factor with a pattern recognition system. Support for the amendment is found in the application as filed at least at page 9, lines 21-23 and page 22, lines 15-17. Otvos does not teach or suggest use of a pattern recognition system to generate a screening factor. Accordingly, the current rejection of Claims 1 and 15 and all claims dependent therefrom under 35 U.S.C. § 102(e) as being anticipated by Otvos is deemed to be overcome.

Claim 28

As to Claim 28, the Applicant respectfully disagrees. Those skilled in the art will immediately understand that a noninvasive blood glucose analyzer does not use a blood sample drawn from the body. Further, dictionary.com defines noninvasive as:

> **non·in·va·sive** Not penetrating the body, as by incision or injection: *noninvasive surgery; a noninvasive diagnostic method.*

Hence, by both definition and as known by those skilled a noninvasive analyzer does not use a blood sample drawn from the body. In stark contrast, the Examiner cites

the abstract of Otvos, which teaches, emphasis added: "A patient blood sample is collected and NMR derived patient spectrums for the blood sample are obtained. [and] The glucose concentration can be evaluated with a blood sample". Thus, Otvos teaches away from the Claim 28 of a noninvasive blood glucose analyzer. The Applicant respectfully points out that according to MPEP 2131 Anticipation requires, emphasis added: "To anticipate a claim, the reference must teach every element of the claim". Further, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Otvos not only does not teach noninvasive, but teaches away from the noninvasive arts into the invasive diagnostic arts. Accordingly, the current rejection of Claim 28 under 35 U.S.C. § 102(e) as being anticipated by Kalatz is deemed to be improper.

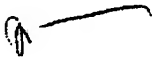
The Applicant amends Claim 28 to properly conform descendent language with antecedent usage according to standard claim drafting practices.

7. Applicant provides herewith a terminal disclaimer of the current application to copending U.S. patent application no. 10/702,710. Accordingly, the provisional double-patenting rejection is deemed to be overcome.

CONCLUSION

In view of the above, the Application is deemed to be in allowable condition. The Examiner is therefore earnestly requested to withdraw all outstanding rejections, allowing the Application to pass to issue as a United States Patent. Should the Examiner have any questions regarding the application, he is respectfully urged to contact Applicant's attorney at (650) 474-8400.

Respectfully submitted,



Michael A. Glenn
Reg. No. 30, 176

Customer No. 22,862